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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,725	01/27/2006	Hideki Tanji	10921.0296USWO	9962
52835 7590 02/21/2007 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902			EXAMINER TURK, NEIL N	
			ART UNIT 1743	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/530,725	Applicant(s) TANJI, HIDEKI	
	Examiner Neil Turk	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/27/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/7/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Remarks

Claims 1-18 are pending. Claims 14-18 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restrictions

Applicant's election of group I, claims 1-13, in the reply filed on November 27th, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: claim 6 recites "a detector", however the in the specification and as shown in figure 3 there are two detectors (referred to as light-sensitive elements in the specification). As currently recited, Examiner will interpret two separate detectors or a single detector that detects both signals to constitute the claimed detector.

Claims 6-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such

omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: Claims 6-13 do not establish structural relationships between the elements so as to allow their respective functions. For example, claim 6 does not establish the structural relationship between the light irradiator, detector, and calculator so as to link the irradiating, detecting, and subsequent calculation functions. The structural relationship between the detector (or as Examiner has asserted, two detectors) the reaction system, and the reference board must also be defined. This is likewise seen in further dependent claim 7, where the storage is not given any structural relationship to the aforementioned elements, as well as the recited selector. Further, the controller as recited in claim 10 is not given any structural relationship to the elements that precede it.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Matzinger (5,780,304).

Matzinger discloses a method and apparatus for analyte detection having an on-strip standard. Matzinger discloses that the invention relates to a test device and method for optically measuring the concentration of glucose in whole blood (lines 8-12,

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col. 1). Matzinger discloses a test strip that has a reaction zone (with color-producing reagent), which varies in reflectance as a function of the quantity of analyte present, and a standard zone that is positioned so as to lead the reaction zone as the strip is inserted into a reading apparatus. Matzinger discloses that the apparatus has optical means for sequentially determining the reflectance value of the standard zone and for determining the reflectance value of the reaction zone after the strip has been inserted. The apparatus further includes means for calculating the presence and/or quantity of the analyte as a function of the standard zone and reaction zone reflectance (abstract; lines 26-60, col. 4; lines 61-67, col. 8; lines 1-31, col. 9). Matzinger discloses the apparatus 12 is provided with a power switch 20 for activating the apparatus and the optics block 32 is affixed to the apparatus and operable to direct light through aperture 30 in rapid bursts, "chops", for a period of time each time it is activated (lines 50-67, col. 5; lines 19-35, col. 6, figs. 1-3). Matzinger discloses that the standard zone 60 provides a calibrated standard reflectance value against which the reflectance of the color-developed reaction zone may be measured so as to allow computation and reporting of the presence or quantity of the analyte (lines 40-67, col. 9; lines 1-21, col. 10; lines 6-28, col. 11; figs. 1, 4, and 6). Matzinger also discloses that the reflectance of the surface presented to the optics is measured at all the various positions and multiple readings are taken at each position in spaced periods of time (lines 30-67, col. 11, figs. 7-11). Matzinger further discloses that the apparatus views the gray target and read a value for its reflectance at each LED wavelength and compare the values to the factory stored values for the gray reading. If there is a difference between the stored readings and the actual readings an

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adjustment is made (lines 36-50, col. 6; lines 5-67, col. 13). Matzinger discloses further calibration measures and checks throughout column 14. Matzinger also discloses that the microprocessor employs a look-up table to provide proper coefficients for calibration of the specific test strip employed in the apparatus to correct K/S ratio (lines 1-60, col. 15). Examiner interprets the function of the microprocessor to check and compare the gray readings against factory-stored values for adjustments to correspond to the selector and calculation corrections as claimed.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8914. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT


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